



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0157]

Study Approaches and Methods to Evaluate the Safety of Drugs and Biological Products During Pregnancy in the Post-Approval Setting; Public Meeting, Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA) is announcing a public meeting entitled "Study Approaches and Methods to Evaluate the Safety of Drugs and Biological Products During Pregnancy in the Post-Approval Setting." The purpose of the public meeting is to engage in constructive dialogue and information sharing among regulators, researchers, the pharmaceutical industry, public health agencies, health care providers, and the general public concerning challenges in designing and implementing pregnancy registries and other methods of evaluating the post-approval safety profile of drugs and biological products in pregnant women. The input from this meeting and public docket will be used to support the revision of a guidance for industry on establishing pregnancy exposure registries.

Dates and Times: The meeting will be held on May 28, 2014, from 8 a.m. to 5 p.m. and May 29, 2014, from 8:30 a.m. to 12:30 p.m.

Location: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD 20993-0002. Participants must enter through Building 1 and undergo security screening. For parking and security information, please visit

<http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>. Please arrive early to ensure time for parking and security screening.

Contact Persons: For meeting background and content: Vicki Moyer, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-6148, FAX: 301-796-9855, vicki.moyer@fda.hhs.gov. For registration, oral presentations, special accommodations, and other meeting logistics: Cherice Holloway, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-4909, FAX 301-796-9832, cherice.holloway@fda.hhs.gov.

Registration and Requests for Oral Presentations: Registration is free and available on a first-come, first-served basis. You must register online by May 14, 2014. Seating is limited, so register early. FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the meeting will be available. To register for this meeting, please visit FDA's Drugs News & Events--Meetings, Conferences & Workshops calendar at <http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm> and select this meeting from the events list. If you need special accommodations due to a disability, please contact Cherice Holloway (see Contact Persons) at least 7 days before the meeting. Those without Internet access should contact Cherice Holloway to register.

This meeting includes a public comment session. If you would like to present during this session, please identify the topic(s) you will address during registration (see Section II).

FDA will do its best to accommodate requests to speak. FDA urges individuals and organizations with common interests to coordinate and give a joint, consolidated presentation. Following the close of registration, FDA will allot time for each presentation and notify

presenters by May 20, 2014. Do not present or distribute commercial or promotional material during the meeting. Registered presenters should check in before the meeting.

Live Webcast of the Meeting: To view the Connect Pro Webcast of this meeting, you must register online by 4 p.m., May 14, 2014. Webcast connections are limited, so register early. Organizations should register all viewers but access the Webcast using one connection per location.

Webcast viewers will be sent system requirements after registration and will be sent connection information after May 21, 2014. Visit https://collaboration.fda.gov/common/help/en/support/meeting_test.htm for the Connect Pro Connection Test. To get a quick overview of Connect Pro, visit http://www.adobe.com/go/connectpro_overview. (FDA has verified the Web site addresses in this notice but is not responsible for any subsequent address changes after this notice publishes in the Federal Register.)

Comments: FDA is holding this meeting to obtain information on study approaches and methods to evaluate the safety of drugs and biological products during pregnancy in the post-approval setting. FDA is soliciting from interested persons electronic or written comments on all aspects of the meeting topics through June 30, 2014.

Attendees and non-attendees may submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Send only one set of comments. When sending comments, please include the docket number from the heading of this notice. In addition, when addressing specific topics (see Section II), please identify the topic. Received comments may be viewed in the Division of Dockets

Management between 9 a.m. and 4 p.m., Monday through Friday and will be posted to the docket at <http://www.regulations.gov>.

Transcripts: After the meeting, FDA will post a transcript at <http://www.regulations.gov>. The transcript may be viewed at the Division of Dockets Management (see Comments). A transcript will also be available in either hardcopy or on CD-ROM after submission of a Freedom of Information request. Send requests to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is holding this meeting to seek input from industry, academia, public health agencies, the clinical community, and other stakeholders regarding the structure and design of pregnancy registries. In addition, other methods of evaluating the safety profile of drugs and biological products in pregnant women in the post-approval setting will be explored.

At the time of initial approval of a drug or biological product, there are generally very limited data on the safety of the product when used during pregnancy. Pregnancy registries provide post-approval safety information. In certain cases, these registries may be post-marketing requirements. The goal of pregnancy registries is to evaluate the risk of birth defects or pregnancy complications related to use of a product and to use these data to inform safety-related product labeling.

The purpose of the meeting is to engage in constructive dialogue and information sharing among regulators, researchers, the pharmaceutical industry, public health agencies, health care providers, and the general public concerning challenges in designing and implementing

pregnancy registries. FDA is seeking feedback on practical approaches to improve pregnancy registries, as well as alternative approaches, to obtain robust scientific information on the rate and occurrence of birth defects or pregnancy complications related to the use of a product.

Additionally, FDA is seeking input on best practices to communicate information to health care providers and patients about pregnancy registries and other post-approval studies in which pregnant women can enroll. Feedback from this meeting will be used to support revision of the current guidance for industry entitled "Establishing Pregnancy Exposure Registries" (August 2002), available at

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM071639.pdf>.

The meeting will include multiple sessions over 2 days.

II. Scope of the Meeting

The objective of the meeting is to engage researchers, industry, public health agencies, health care providers, and the public through presentations and panel discussions on the following topics:

- Current status of pregnancy registries and challenges in gathering data regarding drug and biological products used during pregnancy. These challenges include, but are not limited to, low enrollment, poor followup rate, limited sample size, ascertainment of adverse outcomes, and appropriate comparator group selection.
- Strategies to improve the design and conduct of pregnancy registries.
- Alternative approaches, such as enhanced pharmacovigilance, claims-based database studies, prospective cohort or case control studies and other innovative methodologies, to

obtain robust scientific information on the rate and occurrence of possible safety concerns related to the use of drugs and biological products during pregnancy.

- Best practices for communicating information to health care providers and patients about pregnancy registries and other post-approval studies.

Information about this meeting, including registration and the agenda, will be posted at <http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm> as it becomes available.

Dated: February 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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